

### **REMARKS/ARGUMENTS**

The Examiner considers there to be 24 distinct inventions in the claims as filed. This is partly because the Examiner considers claim 1 to encompass two separate inventions, a particulate composition comprising components a), b) and c) (labelled as claim 1A), and a particulate composition comprising components a) and c) only where a) comprises two components (labelled as claim 1B). In view of this, the Examiner has broken down the claim set as follows.

Claim 2 is designated as Group I, directed to a particulate composition comprising at least 50% of at least one structure forming amphiphile, 2-40 % of at least one structure swelling amphiphile and 2-20% of at least one dispersion stabilising polymeric amphiphile, wherein the composition comprises non-lamellar particles or forms non-lamellar particles when contacted with an aqueous fluid.

Claims 3-11 are each designated as a separate invention, Groups II-X respectively, in respect of compositions according to claim 1A.

Claims 12-13 and 14-15 are designated as Groups XI and XII respectively, in respect of compositions according to claim 1A.

Claims 16 and 17 are designated as Groups XIII and XIV respectively, in respect of a pharmaceutical formulation and a kit comprising compositions according to claim 1A.

Claims 5, 7, 8, 9, 10 and 11 are each designated as a separate group, Groups XV to XX respectively, in respect of compositions according to claim 1B.

Claims 12-13 and 14-15 are designated as Groups XXI and XXII respectively, in respect of compositions according to claim 1B.

Claims 16 and 17 are designated as Groups XXIII and XXIV respectively, in respect of a pharmaceutical formulation and a kit comprising compositions according to claim 1B.

The Examiner explains that he does not consider the inventions to share a special technical feature which is novel and inventive over the prior art, in view of US 6537575 (Firestone *et al*) and US 6593294 (Baru *et al*). As discussed in the Office Action, Claim 1A links Groups I-XIV and the restriction requirement is subject to the non-allowance of Claim 1A. Groups XV to XXIV are linked by Claim 1B, and this restriction requirement is also subject to the non-allowance of Claim 1A. In other words, if Claim 1A is eventually allowed, the restriction requirements will be dropped.

Applicants elect claim 2.

The Examiner indicates that the Groups will all be rejoined if the main claim is allowed. Applicants traverse the restriction requirement to ensure the opportunity to rejoin the claims after allowability and/or allowance.

The Examiner also requires species elections in respect of claims 5 (lipid component), 6 (swelling agent), 7 (polymeric agent), and 8 (L3 or reversed hexagonal phase).

Applicants' choices are:

Phospholipids - as lipid component (claim 5)

PEG Sorbitan fatty acid esters - as swelling agent (claim 6)

Poloxamers - as polymeric agent (claim 7)

Reversed hexagonal - as phase (claim 8).

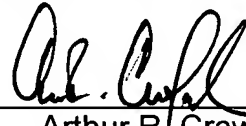
JOHNSSON ET AL.  
Appl. No. 10/586,777  
December 6, 2010

Please examine the elected subject matter taking into account the documents cited during the examination of the International Application, as cited in the Preliminary Amendment of July 21, 2006 and listed on PTO/SB/08a submitted with that Amendment.

Respectfully submitted,

**NIXON & VANDERHYTE P.C.**

By: \_\_\_\_\_



Arthur R. Crawford  
Reg. No. 25,327

ARC:sjg  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100